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EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/646,442

**Applicant(s)**

KUCKLICK ET AL.

**Examiner**

Bhisma Mehta

**Art Unit**

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 3, 4, 8, 9, and 11-22 are objected to because of the following informalities:

a. In line 4 of claims 3, 4, 8, 9, 18, and 19, there appears to be a grammatical error in the phrase "length if the slot."

b. Claim 11 recites the limitation "the distal end of the tube" in line 30. There is insufficient antecedent basis for this limitation in the claim. The recitation of the limitations "the distal portion of the tube" in line 22, "the tube" in line 24, "the lumen of the tube" in line 27-28, "said tube" in line 29, and "the distal end of the tube" in line 30 makes it unclear as to which tube (the rigid or flexible) and as to which lumen (the lumen of the rigid tube or the lumen of the flexible tube) applicant is referring to. For example, it appears that in line 22, applicant is referring to a distal portion of the flexible tube. For clarity, applicant should establish a distal portion for the flexible tube. Additionally, the use of "the flexible tube", "the rigid tube", "the lumen of the flexible tube", and "the lumen of the rigid tube" would make it clear as to which tube and as to which lumen applicant is referring to.

c. Claim 13 recites the limitation "the distal end of the tube" in line 4. There is insufficient antecedent basis for this limitation in the claim.

a. Claim 20 recites the limitation "the distal portion of the rigid tube" in lines 17-18. There is insufficient antecedent basis for this limitation in the claim.

d. Claim 22 recites the limitation "the lumen" in line 37 of the claim. There is insufficient antecedent basis for this limitation in the claim. There is no positive recitation of a lumen in the surgical instrument port established in line 3. The recitation of the limitations "the lumen of the tube" in line 32, "said tube" in line 33, and "the distal end of the tube" in line 34 make it unclear as to which tube (the rigid or flexible) and as to which lumen (the lumen of the rigid tube or of the flexible tube) applicant is referring to. See the paragraph b for suggestions on clarifying the claim.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 5, 6, 8, 10, 11, 13, 15-18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce (U.S. 5,800,409) in view of Clement et al (U.S. 5,203,769). In Figures 2 and 5, Bruce show a rigid tube (26) having a lumen (39), a valve (44), and a cannula attached to the distal portion of the rigid tube and having a flexible tube (14) where the distal portion of the tube has a row of slots (34) disposed along a longitudinal line of the tube and where the slots are in fluid communication with the lumen (38) of the tube. As to claim 5, in Figure 2, a plurality of circumferential

Art Unit: 3767

grooves are shown between each of the slots (34) and each groove is disposed around the entire circumference of the tube. As to claims 10 and 13, in lines 31-38 of column 3, Bruce teaches that the tube (14) is tapered such that the thickness of the tube tapers along the direction of the distal end of the tube thus allowing the tube to become increasingly flexible in that direction. As to claim 15, the cannula is considered to be removably attached to the rigid tube as Bruce states that the preferred embodiment would be a single piece instrument and thus another embodiment would be one in which the cannula is removable. In lines 1-10, Bruce discloses that other materials having the requisite flexibility properties may also be used to manufacture the cannula. This would be the embodiment where the cannula would be removably attached to the rigid tube, as the material used for the cannula would not necessarily be the same material that could be used for the rigid housing. As to claim 16, in Figure 2, a fluid port (42) is in fluid communication with the lumen of the rigid tube. As to claims 20 and 21, in Figure 5, a surgical instrument (54) with a curved distal portion is shown inserted into a surgical instrument port and extending through the lumen of the rigid tube and the lumen of the cannula. Bruce also teaches using the rigid tube, valve, and cannula to perform an arthroscopic surgery procedure as claimed in claim 22.

As to claims 1, 3, 6, 8, 11, and 18, Bruce discloses the surgical instrument port having a rigid tube (26), a valve (44), a cannula (14), and a surgical instrument (54) and the method of performing the arthroscopic surgery procedure substantially as claimed. However, Bruce does not disclose the cannula having a plurality of longitudinally staggered rows of slots. Clement et al disclose a surgical instrument port system as

Art Unit: 3767

shown in Figure 11 having a rigid tube (12), a valve (50), and a flexible cannula (200) where the distal portion (202) of the cannula has a plurality of longitudinally staggered rows of slots (204) which are longitudinally aligned with each other. Clement et al also teach that the slots may be longitudinally oriented as shown in Figure 27 where each slot is narrower in a first direction (circumferential length of the slot) as compared to a second direction (longitudinal length of the slot). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the row of slots on the cannula of Bruce with a plurality of longitudinally staggered rows of slots which are longitudinally aligned with each other as taught by Clement et al as both Bruce and Clement et al teach using the slots on the cannula for introducing and removing fluid from a surgical site and Clement et al teach that it is advantageous to use a plurality of longitudinally staggered rows of slots which are longitudinally aligned with each other on the cannula. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the slots of Bruce with the longitudinally oriented slots as taught by Clement et al as Clement et al teach that fluid can be delivered to a surgical site through a variety of slot configurations, including longitudinally oriented slots.

As to claim 17, even though Bruce discloses using a valve for controlling the flow of fluid to and from a surgical site, Bruce does not teach using a clamp which is operably connected to the rigid tube and which can be used to restrict the flow of fluid through the instrument port. Clement et al teach using a clamp (60) which is operably connected to the rigid tube (12) and which can be used to restrict the flow of fluid

Art Unit: 3767

through the instrument port. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the instrument port of Bruce with a clamp as taught by Clement et al as a means to control the flow of fluid to and from a surgical site.

4. Claims 2, 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce in view of Clement et al as applied to claims 1 and 11 above, and further in view of Theeuwes et al (U.S. 6,638,263). Bruce and Clement et al disclose the invention substantially as claimed. However, Bruce and Clement et al are silent on the proximal portion of the tube having a plurality of circumferential ridges. In lines 13-54 of column 14, Theeuwes et al teach that a catheter may be tapered at the distal end relative to the proximal end to allow the catheter to be more flexible and more easily inserted into a surgical site and also teach that the outer surface of the catheter may have a plurality of circumferential ridges which would be desirable for specific applications. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the proximal portion of the cannula of Bruce with a plurality of circumferential ridges as taught by Theeuwes et al as both Bruce and Theeuwes et al teach that it is desirable to have a more flexible distal portion on a tube that is to be inserted into a body and Theeuwes et al teach in lines 13-26 that it is well known that circumferential ridges can be placed on the outer surface of a tube as such a variation may be desirable for the specific application for which the tube will be used.
5. Claims 4, 9, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce in view of Clement et al as applied to claims 1 and 11 above, and further in



Art Unit: 3767

view of Ott (U.S. 6,733,479). Bruce and Clement et al disclose the invention substantially as claimed. Even though Bruce discloses a cannula having a plurality of slots, Bruce is silent on the slots being circumferentially oriented. Ott discloses a tube having circumferentially oriented slots where each slot is narrower in a first direction (longitudinal length of the slot) as compared to a second direction (circumferential length of the slot) as shown in Figures 5 and 7. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the slots of Bruce with the circumferentially oriented slots as taught by Ott as Ott teaches in lines 26-47 of column 7 that fluid can be delivered to a surgical site through a variety of slot configurations including circumferentially oriented slots.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce in view of Clement et al as applied to claim 11 above, and further in view of Davis et al (U.S. 6,159,182). Bruce and Clement et al disclose the invention substantially as claimed. Bruce discloses using a valve for controlling the flow of fluid to and from a surgical site and for allowing a surgical instrument to be inserted through the cannula. However, Bruce does not teach the valve being a duckbill valve. In lines 40-59 of column 1, Davis et al teach using a duckbill valve which is operably connected with a cannula and which can be used to allow a surgical instrument to be inserted through the cannula without allowing flow of fluid through the valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the valve of Bruce with the duckbill valve as taught by Davis et al as Davis et al teach that it



Art Unit: 3767

is well known to use duckbill valves to control fluid flow when a surgical instrument is inserted into a cannula.

### ***Response to Arguments***

7. Applicant's arguments, see line 10 of page 16 to line 8 of page 17, filed August 15<sup>th</sup> 2006, with respect to the prior art rejection of claims 1, 3, 11, 13, 16, 18, and 20-22 as being anticipated by Samson et al (U.S. Patent No. 5,782,811) have been fully considered and are persuasive. The rejection of these claims as being anticipated by Samson et al has been withdrawn.

8. Applicant's arguments filed August 15<sup>th</sup> 2006 with regards to the prior art rejection of claims 1-22 in view of Bruce, Clement et al, Theeuwes et al, Ott, and Davie et al have been fully considered but they are not persuasive. Clement et al do not only disclose the use of round or circular apertures or slots. In Figure 27, Clement et al show longitudinally oriented slots where each slot is narrower in a first direction (circumferential length of the slot) as compared to a second direction (longitudinal length of the slot). In Figure 11, the slots of Clement et al are considered to be arranged in a plurality of longitudinally staggered rows. The slots are not all aligned with one another in adjacent rows as at least some slots are staggered with respect to others. Also, the rows are considered to be staggered as each row is arranged to be staggered behind a preceding row. Applicant's arguments on page 19 are not persuasive because Ott does show staggered slots in Figure 7 and circumferentially oriented slots where each slot is narrower in a first direction (longitudinal length of the

Art Unit: 3767

slot) as compared to a second direction (circumferential length of the slot) in Figures 5 and 7.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

Art Unit: 3767

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

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SUPERVISORY PATENT EXAMINER

